

S.N. 09/252,322

REMARKS**I. APPLICANTS' INVENTION**

The present invention relates to a catheter balloon comprised of a composite of PTFE film and an elastomer. The balloon simultaneously offers high strength (able to withstand inflation to high pressures) with the behavior of a elastic, low pressure latex balloon in that it does not require folding around the catheter shaft for insertion at a minimum diameter (as do conventional polyethylene terephthalate high pressure catheter balloons). Following inflation and during subsequent deflation, the balloon returns to its original pre-inflation small diameter without wrinkles, again in the fashion of a low pressure elastic (latex) balloon.

II. REJECTION OF CLAIMS 25, 26, 32, 33, 39, 43, 44, 56 AND 59 UNDER 35 USC 102(b) AS ANTICIPATED BY KAMEN, US 3,640,282.

The Examiner states that Kamen discloses a balloon made from two materials, an outer layer made of elastic material and an inner porous layer. The inner porous layer is a resilient spongelike material that occupies the entire interior space of the balloon when the balloon is inflated; see col. 3, lines 60-66; col. 4, lines 17-25 and Figures 2-5. The present claims, as amended, require the presence of PTFE film. These films, as thin materials, are incapable of occupying the entire interior space of the inflated balloon as taught by Kamen. Accordingly, the present claims as amended are not anticipated by Kamen.

III. REJECTION OF CLAIMS 25, 27, 32, 33, 47, 52, 53, 56 AND 59 UNDER 35 USC 102(b) AS ANTICIPATED BY NOGUCHI et al., US 5,201,706.

The Examiner states that Noguchi discloses a balloon made out of a plurality of layers wherein an outer layer is elastic and a middle layer is a woven yarn construction including both an elastic yarn and an inelastic yarn, wherein the inelastic yarn may be Teflon®. An inner layer is also provided, which is another elastic layer. See col. 1, lines 56-60, col. 3, line 67-col. 4, line 4 and Figure 3.

The present claims as amended require a PTFE film, sealed with an elastomer to render it liquid-tight. Noguchi et al. do not teach or suggest the possibility of making a balloon from such a sealed PTFE film.

IV. REJECTION OF CLAIMS 1-4, 7, 28-31, 41 AND 42 UNDER 35 USC 103(a) AS UNPATENTABLE OVER KAMEN, US 3,640,282.

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Kamen is described above. The Examiner states that Kamen discloses the present invention with the exception of the burst pressure, adding that the burst pressure would have been obvious in light of the construction taught by Kamen.

As amended, the present claims require (as noted above) a PTFE film sealed with an elastomer to render it liquid-tight. Kamen does not teach or suggest in any way the use of such a film. Also as noted above in reference to the anticipation rejection based on Kamen, the entire interior space of the inflated Kamen balloon is occupied by the sponge-like resilient material. The use of the thin PTFE film in the present invention results in the interior space of the balloon, during inflation, being only occupied by the inflating medium. Accordingly, as amended, the present claims are not obvious over the Kamen reference.

V. REJECTION OF CLAIMS 1-24, 26, 28-31, 34-46, 48-51, 54, 55, 57, 58 AND 60-62 UNDER 35 USC 103(a) AS UNPATENTABLE OVER NOGUCHI et al., US 5,201,706.

Noguchi et al. is described above. The Examiner concludes that, given the construction taught by Noguchi et al., it would be obvious to create the claimed present invention having the required burst pressures and compaction ratios. As Noguchi et al. do not teach or suggest in any way the use of a PTFE film, sealed by an elastomer to render the film liquid-tight, to make a catheter balloon, the present claims as amended are not obvious in light of this reference.

CONCLUSION

Applicants submit that their claims are patentable over the cited art and are in condition for allowance. Accordingly, Applicants respectfully request reexamination and passage of the claims to issuance.

If any issues of substance are seen to remain following consideration of the arguments presented herein, in the interest of expedient resolution the Examiner is requested to telephone the Applicants' representative at the telephone number given below, between the hours of 8AM to 5PM Mountain Standard Time.

Respectfully submitted,



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